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| APPLICATION NO.        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|------------------------|-------------|----------------------|---------------------|------------------|--|
| 10/749,296             | 12/31/2003  | Maurice Behague      | 069208.0116         | 9789             |  |
| 23640                  | 7590        | 10/16/2006           | EXAMINER            |                  |  |
| BAKER BOTTS, LLP       |             |                      |                     | CRAIG, PAULA L   |  |
| 910 LOUISIANA          |             |                      |                     | ART UNIT         |  |
| HOUSTON, TX 77002-4995 |             |                      |                     | 3761             |  |
|                        |             |                      |                     | PAPER NUMBER     |  |

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | Application No. | Applicant(s)   |
|------------------------------|-----------------|----------------|
|                              | 10/749,296      | BEHAGUE ET AL. |
| Examiner                     | Art Unit        |                |
| Paula L. Craig               | 3761            |                |

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 07 August 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-15 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-15 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 31 December 2003 is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/25/04.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 5, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,385,630 to Gilcher et al.
3. For Claim 1, Gilcher '630 teaches a bag system including a collection machine including a peristaltic pump (blood donor system 10, Figs. 1-2, Abstract, and col. 4, lines 8-11). A collection device is operable to collect a biological fluid (phlebotomy needle 14, Fig. 1, col. 4, lines 11-32). Gilcher teaches a solution bag containing an anticoagulant (anticoagulant pouch 22, Fig. 1 and col. 4, lines 49-67). A collection bag is operable to receive the biological fluid collected and the anticoagulant solution (collection bag 38, Fig. 1 and col. 5, lines 16-20). A first flexible tube provides fluid communication between the collection device and the collection bag (tubing 40, Fig. 1 and col. 4, lines 38-40). A second flexible tube provides fluid communication between the solution bag and the collection bag (tubing 18, Fig. 1 and col. 4, lines 33-38). Gilcher '630 teaches a connector connecting the first and second flexible tubes (Y-junction 15, Fig. 1 and col. 4, lines 13-18). An association device is operable to form a loop with the second flexible tube between the association device and the connector (association device is

rollers 8 and pump platen 26 of pump 24; the loop is formed by tubing 18 and tubing 40; Fig. 1 and col. 4, lines 41-48). The loop has a conformation operable to allow its disposition around the head of a peristaltic pump (Fig. 1 and col. 4, lines 40-48). The system has a closed circuit (Fig. 1, col. 5, lines 17-20, and col. 7, lines 39-51).

4. For Claim 2, Gilcher '630 teaches a three way connector to which a downstream end of an upstream part of the first tube, an upstream end of the downstream part of the first tube, and a downstream end of a second tube are connected (Y-junction 15, Fig. 1 and col. 4, lines 13-40, and col. 5, lines 17-20).

5. For Claim 3, Gilcher '630 teaches the association device includes a piece having an object operable to associate the device on the second tube and an object operable to associate the first tube on the piece (the piece is pump 24; the objects are the rollers 8 and pump platen 26, Fig. 1 and col. 4, lines 41-48).

6. For Claim 5, Gilcher '630 teaches the objects being operable to allow fixation of the loop (Fig. 1 and col. 4, lines 41-48).

7. For Claim 11, Gilcher '630 teaches a circuit opener disposed near an upstream end of the second tube (outlet of pouch 22, including small round ball, Fig. 1 and col. 4, lines 49-60).

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilcher '630.

11. For Claim 12, Gilcher '630 teaches all the limitations of Claim 1, as described above in paragraph 3. Gilcher does not expressly teach the length of the first tube between the connector and an inlet orifice of the collection bag being greater than 15 cm. The length of the blood tubing is a result effective variable, since it affects where the donor may be placed with respect to the system. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980). It would have been obvious to one of ordinary skill in the art to provide a suitable length of tubing to reach the donor.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilcher '630 in view of U.S. Patent No. 4,558,996 to Becker.

13. For Claim 4, Gilcher '630 teaches all the limitations of Claim 3, as described above in paragraph 5. Gilcher teaches the system being sterile (col. 4, lines 52-55).

Gilcher '630 does not expressly teach the piece being molded from a sterilizable plastics material. However, the use of sterilizable plastics material in bag systems is well known in the art. Applicant's specification indicates that polycarbonate is a suitable sterilizable plastic material (page 11, lines 11-12). Becker teaches a piece molded from polycarbonate (Fig. 6, col. 5, lines 39-46, and Claim 21). It would have been obvious to one of ordinary skill in the art to modify Gilcher '630 to include the piece being molded from a sterilizable plastics material, as taught by Becker.

14. Claims 6, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilcher '630 in view of U.S. Patent No. 5,309,604 to Poulsen.

15. For Claim 6, Gilcher '630 teaches all the limitations of Claim 3, as described above in paragraph 5. Gilcher '630 teaches the association device reversibly associating the first tube on the piece (Figs. 1-6, col. 4, line 41 to col. 5, line 21). Gilcher '630 does not teach the association device having an object operable to nonreversibly associate the device on the second tube. Poulsen teaches an association device for holding medical tubes in place, helping to keep them neat and sterile (Figs. 1-6, col. 1, lines 5-25, and col. 3, lines 47-62). Poulsen teaches one of the tubes being nonreversibly held in place (by passing through bore 30, Figs. 1-6 and col. 3, line 63 to col. 4, line 3). Poulsen teaches another tube being reversibly held in place (by means of the first and second C-clips, Figs. 1-6 and col. 4, lines 4-42). It would have been obvious to one skilled in the art to modify Gilcher '630 to include an association device having an object operable to nonreversibly associate the device on the second tube and

an object operable to reversibly associate the first tube on the piece, as taught by Poulsen, to hold the tubes in place and keep them neat and sterile, as taught by Poulsen.

16. For Claim 7, Gilcher '630 does not teach the piece including a tubular housing forming an object operable to receive the second tube by inserting the second tube into the housing, and a lateral U-shaped housing operable to receive the first tube by snapping the first tube into the housing. Poulsen teaches an association device for holding medical tubes in place, helping to keep them neat and sterile (Figs. 1-6, col. 1, lines 5-25, and col. 3, lines 47-62). Poulsen teaches the association device having a piece with a tubular housing forming an object operable to receive a tube by inserting the tube into the housing (bore 30, Figs. 1-6 and col. 3, line 63 to col. 4, line 3). Poulsen teaches a lateral U-shaped housing operable to receive another tube by snapping the tube into the housing (first C-clip, Figs. 1-6 and col. 4, lines 4-29). It would have been obvious to modify Gilcher '630 to include an association device having a piece with a tubular housing forming an object operable to receive a tube by inserting the tube into the housing, and a lateral U-shaped housing operable to receive another tube by snapping the tube into the housing, as taught by Poulsen, to hold the tubes in place and keep them neat and sterile, as taught by Poulsen.

17. For Claim 8, Gilcher '630 does not teach the piece being associated with the first tube by snapping a downstream part of the first tube into the lateral housing. Poulsen teaches the piece being associated with a tube by snapping a part of the tube into the lateral housing (first C-clip, Figs. 1-6 and col. 4, lines 4-29). Poulsen teaches the

association device for holding medical tubes in place, helping to keep them neat and sterile (Figs. 1-6, col. 1, lines 5-25, and col. 3, lines 47-62). It would have been obvious to one of ordinary skill in the art to modify Gilcher '630 to include using the association device of Poulsen at any point where trailing or untidy tubes were a problem, such as the downstream part of the first tube, to hold the tubes in place and keep them neat and sterile, as taught by Poulsen.

18. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilcher '630 in view of U.S. Patent No. 5,868,696 to Giesler et al.

19. For Claims 9 and 10, Gilcher '630 teaches all the limitations of Claim 1, as described above in paragraph 3. Gilcher '630 does not expressly teach the connector and association device formed as a single piece, nor the piece being a five-way junction having two distinct flow paths. Giesler teaches a bag system having a connector and association device formed as a single piece, and the piece being a five-way junction with two distinct flow paths (piece is the organizer tray 26, Figs. 10-12 and col. 8, line 52 to col. 10, line 6). Giesler teaches that the connector and association device give an organized appearance to a conglomeration of tubing and components (col. 10, lines 1-6). It would have been obvious to one of ordinary skill in the art to modify Gilcher '630 to include the connector and association device formed as a single piece, and the piece being a five-way junction with two distinct flow paths, as taught by Giesler, to give an organized appearance, as taught by Giesler.

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilcher '630 in view of U.S. Patent No. 5,215,450 to Tamari.

21. For Claim 13, Gilcher '630 does not teach a part of the second tube forming the loop having a hardness less than that of the first tube. However, it is well known in the art of peristaltic pumps to have part or all of the tubing in the area of the pump have a hardness less than that of other tubes in the system. Tamari teaches a peristaltic pump for use with blood, with a peristaltic pump tube having a part with a hardness less than that of other tubes in the system (thin wall section has a hardness less than other tubes in the system, Figs. 2a-8b, Abstract, col. 25, lines 5-8). Tamari teaches that the thin wall tubing in the area of the pump decreases the torque required to squeeze the tubing and extends tubing pumping life (col. 17, lines 46-68, col. 22, lines 42-45). It would have been obvious to one of ordinary skill in the art to modify Gilcher '630 to include a part of the second tube forming the loop having a hardness less than that of the first tube, as taught by Tamari, to decrease the torque required to squeeze the tubing and extend tubing pumping life, as taught by Tamari.

22. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilcher '630 in view of U.S. Patent No. 4,596,657 to Wisdom.

23. For Claim 14, Gilcher '630 teaches all the limitations of Claim 1, as described above in paragraph 3. Gilcher '630 teaches a satellite bag (pressure bag 28, Fig. 1 and col. 5, lines 21-33). Gilcher '630 does not teach the satellite bag having a filter. However, satellite bags with filters are well known in the art. Wisdom confirms this and

teaches a blood bag system having a collection bag, a satellite bag, a filter, and a third tube providing fluid communication between the satellite bag and the collection bag (collection bag is donor bag 12, satellite bag is satellite bag 16, filter is filtering means 26, third tube is tube 18; Figs. 1-2 and col. 2, lines 61-68). Wisdom teaches that filtering removes platelets and white cells and provides extended storage life of red cells (col. 2, lines 27-41). It would have been obvious to one of ordinary skill in the art to modify Gilcher '630 to include a subsystem with a satellite bag, a filter, and a connecting tube, as taught by Wisdom, for filtering to remove platelets and white cells and provide extended storage life for red cells, as taught by Wisdom.

24. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilcher '630 in view of U.S. Patent No. 6,113,554 to Gilcher et al.

25. For Claim 15, Gilcher '630 teaches all the limitations of Claim 1, as described above in paragraph 3. Gilcher '630 does not teach a subsystem operable to allow sampling of the biological fluid. However, subsystems for sampling are well known in the art. Gilcher '554 teaches a bag system with a collection machine including a peristaltic pump, a solution bag, a collection bag, first and second flexible tubes, an association device, and a closed circuit (Figs. 1, 3, 4, and 5 and col. 3, lines 26-67). Gilcher '554 teaches a subsystem operable to allow sampling of the biological fluid disposed on the first tube upstream of the connector (pre-sample pouch 168 and tube 166, Figs. 1 and 4 and col. 6, lines 15-26). Gilcher '554 teaches that the sampling subsystem allows for collection of a sample of a donor's blood without a separate

venipuncture (col. 6, lines 15-21). It would have been obvious to one of ordinary skill in the art to modify Gilcher '630 to include a subsystem to allow sampling of the biological fluid disposed on the first tube upstream of the connector, as taught by Gilcher '554, to allow for collection of a sample of a donor's blood without a separate venipuncture.

### ***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,379,452 to DeVries teaches a 5-way connector. The remaining prior art references listed on the accompanying Form PTO-892 show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571)272-5964. The examiner can normally be reached on 6:30AM-3:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig  
Examiner  
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PLC

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